

# **EXHIBIT M**

**Apfel and Meyers Reports' rebuttal of Fleischer Report**

Fleischer Report	Rebuttal in Apfel Report	Rebuttal in Meyers Report
<p>¶82: “As of June 6, 2010, however, DRL’s ANDA was not approved or even eligible for tentative approval as OGD had not reviewed the pending monograph change and how it might apply to DRL’s ANDA. OGD would have had to review DRL’s drug substance to ascertain if it complied with the pending monograph. Since the noncompliance with the monograph was deemed a major deficiency, it is highly likely that the FDA would have considered the June 2, 2010 General Correspondence as a major amendment and relegated the ANDA to the bottom of the review queue.”</p> <p>¶88: Fleischer references email communications from DRL to the FDA regarding the status of the USP pending monograph for an amorphous form of esomeprazole magnesium, as evidence of DRL’s deficiencies with its ANDA. Fleischer concludes, “an authorized pending monograph was finally published on or about December 29, 2010.”</p> <p>¶118: Fleischer summarizes the history of the USP monograph for esomeprazole magnesium and discusses two impacts of the monograph on DRL’s ANDA. Fleischer</p>	<p>¶¶12, 32-36: Rebuts Fleischer ¶¶82, 88, and 118 by providing opinion that in but-for world, DRL would have petitioned the USP during the comment period for the December 2008 monograph to include the amorphous forms of esomeprazole and that it is “much more than likely than not” that the USP would have included the amorphous forms of the esomeprazole magnesium in the official monograph and therefore “it is much more likely than not” that the official USP monograph would not serve as a barrier to DRL marketing its form of esomeprazole magnesium.</p>	<p>¶¶23-24, 48-57, 72-76: Rebuts Fleischer ¶¶82, 88, and 118 by providing opinion that there were no bioequivalency impediments to tentative FDA approval of DRL’s ANDA by the third quarter of 2008 (which was before the USP’s adoption of the trihydrate monograph), and indeed in 2007, given the nature of the bioequivalence deficiencies communicated to DRL by the FDA.</p>

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concludes, “[t]he FDA required compliance with the monograph and DRL’s non-compliance resulted in the OGD suspending review of the ANDA and identified their response of July 14, 2009 as a MAJOR deficiency.”		
<p>¶¶98: “I understand that Plaintiffs and certain of their experts assert that DRL (or an unnamed generic) could have entered the market with esomeprazole in June-July 2011. However, . . . around the time frame of June-July, 2011, DRL’s original ANDA was not approvable as the dissolution failure and increase in the impurity required further investigation.”</p> <p>¶¶123: Fleischer references a bioequivalency deficiency letter dated November 28, 2006, from the OGD in which the OGD transmitted the FDA-recommended method and specifications for dissolution testing of esomeprazole magnesium delayed-release capsules. Fleischer explains DRL’s failure with dissolution testing and that DRL would “very likely reformulate the product and/or alter the manufacturing process.”</p>	<p>¶¶11, 27-31: Rebuts Fleischer ¶¶98, 123 by providing opinion that following a but-for world Ranbaxy launch in November 2008, and in light of DRL’s already-known problems with Cipla (its original source for esomeprazole magnesium and ultimate cause of its testing problems), starting in November 2008 DRL would have sought a new source for esomeprazole magnesium or would have manufactured it itself, allowing tentative approval by October 2009.</p>	<p>¶¶51, 75: Rebuts Fleischer ¶¶98, 123 by saying that OGD bioequivalence deficiencies of November 2006, (recommending dissolution testing and specifications) were typical and consistent for OGD and that “regulatory correspondence was minimal and routine for both dissolution testing and bioequivalence studies,” and that “to my knowledge, the three minor comments would have been easily addressed.” Provides opinion that there were no bioequivalence issues that would have prevented tentative approval in 2007.</p>
<p>¶¶113, 114: Fleischer summarizes deficiencies with DRL’s ANDA, including the need for a new sprinkle study, and concludes “As of the date</p>	<p>¶¶11, 27-31: Rebuts Fleischer ¶¶113, 114 by providing opinion that following a but-for world Ranbaxy launch in November 2008, and in light</p>	

Fleischer Report	Rebuttal in Apfel Report	Rebuttal in Meyers Report
<p>of this report, I am not aware that DRL has an ANDA for esomeprazole magnesium capsules that could be found approvable by the OGD.”</p> <p>Fleischer further summarizes deficiencies with DRL’s ANDA, including issues with dissolution failures and impurity problems and concludes, “Therefore, as of the date of this report, DRL does not have a product to submit for review.”</p>	<p>of DRL’s already-known problems with Cipla (its original source for esomeprazole magnesium and ultimate cause of its testing problems), starting in November 2008 DRL would have sought a new source for esomeprazole magnesium or would have manufactured it itself, allowing tentative approval by October 2009.</p>	